

North Carolina Department of Health and Human Services Division of Health Service Regulation

Pat McCrory Governor Aldona Z. Wos, M.D. Ambassador (Ret.) Secretary DHHS

> Drexdal Pratt Division Director

RESPONSE REQUIRED

January 3, 2014

Elizabeth Kirkman 2709 Water Ridge Parkway, Suite 200 Charlotte, NC 28217

Conditional Approval

Project I.D. #: F-10218-13

Facility: Randolph Surgery Center

Project Description: Relocate two dedicated outpatient operating rooms from Carolinas

Medical Center to Randolph Surgery Center, a new separately licensed ambulatory surgical facility with two operating rooms and one procedure

room

County: Mecklenburg FID #: 130489

Dear Ms. Kirkman:

The Certificate of Need (CON) Section, Division of Health Service Regulation, Department of Health and Human Services has conditionally approved the above referenced certificate of need application. This decision was made after a review of the applications submitted for this cycle and after consideration of the Certificate of Need Law, G.S. 131E-175 et. seq. and regulations promulgated there under, the State Medical Facilities Plan, and other applicable information. Attached to this letter are the required findings made with respect to your application. The applicant shall not proceed with the construction, offering or development of this project until the certificate of need is issued. Further, the Department shall not issue the certificate of need until all applicable conditions of approval that can be satisfied before issuance of the certificate of need have been met pursuant to G.S. 131E-187(a). The conditions are as follows:

1. Randolph Surgery Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall materially comply with all representations made in its certificate of need application and the clarifying supplemental information dated December 19, 2013. In those instances where representations conflict, Randolph Surgery



Certificate of Need Section

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Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall materially comply with the last-made representation.

- 2. Randolph Surgery Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall develop an ambulatory surgical facility which shall be licensed for no more than two dedicated outpatient operating rooms and one procedure room.
- 3. Randolph Surgery Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall develop no more than two rooms in the facility that meet licensure requirements for an operating room under the ambulatory surgical facility rules.
- 4. Randolph Surgery Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall relocate no more than two dedicated outpatient operating rooms from CMC-One Day Surgery at Carolinas Medical Center.
- 5. Upon completion of the project, The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall take steps necessary to de-license two dedicated outpatient operating rooms located at Carolinas Medical Center and Carolinas Medical Center shall be licensed for a total of no more than 15 shared operating rooms at CMC-Mercy; and 45 operating rooms at CMC-Main, including one dedicated inpatient, four dedicated C-Section, five dedicated Open Heart, 26 shared operating rooms and nine dedicated outpatient operating rooms.
- 6. The procedure room shall not be used for procedures that should be performed only in an operating room based on current standards of practice.
- 7. Procedures performed in the minor procedure rooms shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.
- 8. Randolph Surgery Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall not perform gastrointestinal endoscopy procedures in the procedure room.
- 9. Randolph Surgery Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall meet all criteria to receive accreditation of the ambulatory surgical facility from The Joint Commission, The Accreditation Association of Ambulatory Health Care or a comparable accreditation authority within two years following completion of the facility.

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- 10. Randolph Surgery Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and which would otherwise require a certificate of need.
- 11. Randolph Surgery Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein in writing to the Certificate of Need Section prior to the issuance of the certificate of need.

Response to the above conditions should be submitted to the CON Section no later than 35 days from the date of the decision. Failure to respond within this time period may result in the CON Section making a determination not to issue a certificate of need for the project referenced above.

The conditional approval is valid only for a capital expenditure of \$3,174,299. If a cost overrun occurs that exceeds the approved capital expenditure amount, a new certificate of need may be required as determined by G.S. 131E-176(16)(e).

The applicant should be aware that according to the Certificate of Need Law any affected person shall have thirty (30) days after the date of decision to file a petition for a contested case on this approval. Further, if you are aggrieved by the conditions of the decision you may file a petition for a contested case hearing in accordance with G.S. 150B, Article 3, as amended. This petition must be filed with the Office of Administrative Hearings, 6714 Mail Service Center, Raleigh, North Carolina 27699-6714 within thirty (30) days of the date of this decision. [Note: Effective October 1, 2009, OAH requires a filing fee with submittal of petitions for contested cases. Please direct all questions regarding this fee to OAH Clerk's Office (919-431-3000).]

G.S. 150B-23 provides that a party filing a petition must also serve a copy of the petition on all parties to the petition. Therefore, if you file a petition for a contested case hearing, you must serve a copy of the petition on the Department of Health and Human Services by mailing a copy of your petition to:

Emery Milliken
Department of Health and Human Services,
Office of Legal Affairs,
Adams Building – Room 154
2001 Mail Service Center
Raleigh, North Carolina, 27699-2001

It is requested that a copy of the petition also be served on the Certificate of Need Section.

The certificate of need will not be issued before the completion of this 30 day period ending February 3, 2014. If a contested case request is received within the thirty (30) day period, the certificate will not be issued until the appeal is resolved (10A NCAC 14C .0208).

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The timetable for completion of the project is the timetable outlined in the certificate of need application, unless an adjustment has been made by the CON Section because the review period was extended. The timetable for this project is as follows:

Obtain Funds Necessary to Undertake Project	May 6, 2014
Completion of Final Drawings and Specifications	August 15, 2014
Contract Award	September 30, 2014
25% Completion of Construction	November 9, 2014
50% Completion of Construction	December 16, 2014
75% Completion of Construction	January 25, 2015
Completion of Construction	March 2, 2015
Occupancy/Operation of Equipment/Certification/Licensure of Facility	April 1, 2015

If the decision is appealed, the timetable set forth in this letter will be adjusted accordingly before the Certificate of Need is issued. Please contact us if any clarification of this decision is required.

Please refer to the Project I.D. # and Facility I.D. # (FID) in all correspondence.

Sincerely,

Celia C. Inman, Project Analyst

Lisa Pittman, Team Leader Certificate of Need Section

CCI:LP:mw

Attachment

cc: Medical Facilities Planning Section, DHSR
Acute & Home Care Licensure & Certification Section, DHSR
Construction Section, DHSR

CERTIFICATE OF SERVICE

I hereby certify that I have served the foregoing notice of **conditional approval** on the following person by placing a copy in an official depository of the United States Postal Service in a postage-paid, first class envelope addressed as follows:

Elizabeth Kirkman 2709 Water Ridge Parkway, Suite 200 Charlotte, NC 28217

> Project I.D. # F-10218-13 FID #130489

This the 3rd day of January, 2014.

Celia C. Inman
Project Analyst